EXHIBIT P

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume I

Washington, D.C.

Thursday, January 24, 2008

9:00 a.m.

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state.
(Exhibit Abbott 461 was marked for identification.)
MR. TORBORG: I'm told that we have five minutes left on the tape and it's within about an hour. So let's go ahead and take a break here.
THE VIDEOGRAPHER: This is the end of tape 4. Off the record at 3:17.
(Recess.)
THE VIDEOGRAPHER: This is the beginning of tape 5 in the deposition of Ms. Gaston. On the record at 3:43.
MR. TORBORG: Welcome back, Ms. Gaston.
THE WITNESS: Thank you.
MR. TORBORG: I wanted to cover something, some housekeeping matters on the record very quickly. I understand from Ms. Martinez that there are some additional documents from Ms. Gaston's files or legacy files that are yet to be produced. Is that right?
MS. MARTINEZ: Yes.

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MR. TORBORG: And those are ones that you're working on currently and we intend to schedule a second day with Ms. Gaston so that we can go over those documents.
MS. MARTINEZ: I believe what you told me is that you'd look at them and see if you need an additional day.
MR. TORBORG: That's true.
MS. MARTINEZ: But naturally --
MR. TORBORG: I will need an additional day anyway.
MS. MARTINEZ: Okay. That's what I thought.
MR. TORBORG: Okay.
BY MR. TORBORG:
Q. Okay. Going back to the subject of federal upper limits, Ms. Gaston, I want to ask just a few very general background questions about how the process worked at HCFA, who was involved in what aspects and things of that nature. Earlier you testified or you identified three people at CMS who were involved in establishing the FULs. I believe

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you said from 1991 through 2003 when you were doing that, correct?
A. Correct.
Q. And those three people were -- three additional people were Peter Rodler, Cindy Bergin and Gail Sexton?
A. Gail Sexton worked on the FULs after 2003.
Q. Did she have any involvement with FULs prior to 2003?
A. No.
Q. What was she doing prior to 2003?
A. I'm not sure. She was employed by CMS around that time, but I don't know exactly when she started.
Q. And Mr. Rodler I understand was somebody who had been at HCFA and the Medicaid Bureau prior to you being there?
A. Correct.
Q. And then at some point he retired or moved on?
A. Correct.

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Q. Do you know when he retired or moved on?
A. No.
Q. Can you give me a sense? Was it early '90s, late '80s?
A. I'm guessing it was in the '90s. Not in the late '90s, but I'm not sure.
Q. And Cindy Bergin, when did she work at CMS on the FUL issues?
A. She was hired -- I'm not sure exactly the date -- probably eight or nine years ago. And I mentored here on the FULs until I left in 2003.
Q. So she would have been someone that was working on FUL issues starting in the mid to late '90s; is that fair to say?
A. That's fair to say.
Q. And did you work with Mr. Rodler on the federal upper limit issues or did you sort of succeed his duties?
A. He taught me how to handle the federal upper limit program. And then when he left I took it over.
Q. And did Cindy Bergin take it over from

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you --
A. Yes.
Q. And then at some point is it your understanding that Gail Sexton took it over from Cindy Bergin or were they both working on it?
A. She -- Cindy trained Gail and then Gail took it over when Cindy left the area.
Q. So it sounds to me -- and please tell me if I'm mischaracterizing this or misunderstanding this -- that the mechanics of the FUL program were handled primarily by one person, but there was some overlap in training. Is that right?
MS. MARTINEZ: Objection, form.
A. Generally speaking. There were periods when it was just one person. And then when there were two, even though one was training they were both working on it.
Q. And did you first get involved -- is it your recollection that a transition between yourself and Mr. Rodler happened in the early '90s; is that fair to say?
A. When Pete retired then I took it over.

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Q. And was there anyone else working on the FUL issues besides yourself from that point until Cindy Bergin came on in the mid to late '90s?
A. There was a period of time where I trained Altamease Arnold, but --
Q. Was she in your office?
A. She was in our office. But she was never -- she never really worked on the program per se.
Q. When you say per se, what do you mean by that? Officially or what does that mean?
A. She never really learned the program to work on it.
Q. What does it mean to learn the program?
A. When you try to teach someone the program but they choose not to absorb what you're teaching.
Q. Got it. Is she still working at CMS?
A. No.
Q. When did she leave CMS?
A. She retired last year.
Q. What was her position at CMS?
A. Health insurance specialist.

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Q. Was that the same position that you had?
A. Yes.
Q. So you were equals, so to speak?
A. Most of the analysts in our area are all health insurance specialists.
Q. Okay. And you indicated that Mr. Reed would have some input into the FULs and I think you used the word even the final say.
A. Correct.
Q. What does that mean?
A. He's the division director.
Q. So what would the extent of his involvement be with FULs? When would he get involved?
A. Throughout -- whenever necessary he was there to discuss issues that might need to be discussed. The final publication he was aware of and would have to give his okay in order to send it through or any letters that would go through generally were from an authority higher than me.
Q. Can you tell me what kind of issues would come up in the FUL program that would necessitate

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his involvement?
A. Maybe just general discussion. Especially when I was the only one working on the FUL program, just a general discussion of maybe particular drugs, the pricing just somebody to have an open discussion about how we're setting the prices, because there's manual review involved.
Q. What do you mean when you say there's manual review involved? And we'll get into a little bit more the mechanics, but generally speaking what do you mean by that?
A. Generally you have paper that you work from. You have the compendia with all the drug numbers on it and the pricing. And sometimes you have to make determinations if it looks like a drug is truly available or not, whether you should follow up and see if it's available. Sometimes it's better to discuss it with someone to see that you're looking at it the same way that they might be looking at it.
Q. When you say truly available, do you remember is the product available from a particular

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manufacturer, whether it be because they quit making the drug or they have a shortage of the drug? Is that what you're talking about?

A. I think what I'm talking about, at least preliminarily, is we have printouts from the compendia. And just looking at the printouts, sometimes there might be pricing that looks like it's not updated in the compendia source. So you might want to discuss and say does this look like it's maybe old pricing, maybe we should follow up and see if it's still available. Has the pricing been updated, is the drug still out there, because a lot of times the compendia might not be totally up to date.

Q. How much of your time, if you could estimate, in your position as a health insurance specialist from '91 to 2003, roughly, did you spend on the FUL program?

A. I really can't say. There was a period of time when we were trying to get a publication out where I could spend the majority of my time working on it. I had other duties, so the FULs couldn't

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take up all of my time every day. It just depended on what activity occurred. You would stop. You would work on the FULs. Then I would go back to my other areas.

Q. Did you work -- are you a five-day employee every week or did you work part time during this time?

A. During the 2003 --

Q. During the '91 through 2003 time period?

A. I was an eight hour a day, five day --

Q. Five day a week employee?

A. Correct.

Q. All right. Could you walk me through the -- let me see if it helps facilitate the discussion to find a document here that might help us talk about this a bit.

(Exhibit Abbott 462 was marked for identification.)

BY MR. TORBORG:

Q. For the record, what I've marked as Abbott Exhibit 462 bears the Bates numbers HHC

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902-0446. Ms. Gaston, if you would take a look at that document and let me know if that's a document that you're familiar with.

A. Yes. I am familiar with it.

Q. Could you tell us what this document is?

A. It looks like it's just an overview of the federal upper limit program.

Q. Did you play a part in drafting this document?

A. I may have. I'm not sure.

Q. Ms. Gaston, can you walk me through basically what you did to establish federal upper limits for drugs? Can you just walk me through the process?

A. Do you want me to use this exhibit?

Q. If it helps --

A. Okay.

Q. -- that would be fine. I'm just trying to have you -- put me back in your office back in the mid-'90s or whenever you were working on this and tell me what you did.

A. Well, first of all we have an

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application. I'm going to talk about it in reference to the application that's used that houses this information. But our systems folks when it's time to set a FUL or put out a new list of FUL drugs, the system folks will obtain the FDA Orange Book data and they'll pull that into their system. And there are some standards within that program that look for the criteria that's sort of detailed in this handout here.

Once that criteria is met then the system will pull in the latest compendia data and then they'll merge the two. And the compendia data, there's some criteria in there too. But they try to match the compendia data to the drugs pulled from the FDA. And they match them together and then the application -- and I'm simplifying this -- but the application will have in there FUL groups, which include like all NDC numbers, and it will have the FUL group, the drug names, the NDC number and then the compendia and the compendia pricing in there.

So it will have the source, if it's Red Book, Blue Book, Medi-Span, and then it will have

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the prices. It will have an AWP price, a direct price or WAC price. If there's not a price it'll just be blank in any of those categories. And then the system, the application itself -- from my recollection -- it's been a while since I've used it. But it will determine a FUL price where it can.

Then we apply some manual review just to assure we have -- there's some edits and I can't remember all of those. But we want to make sure that it's using -- because it's supposed to use the lowest price in published compendia, and we want to make sure that that lowest price is a true price, that it's using a true price to establish a FUL.

So there's a manual review that's applied to some of the drugs where the pricing might not look right in there or there's missing pricing. But basically there's a lot of manual review that's included before the final FUL listing will come out.

Q. Okay. I appreciate that. I'm going to try to follow up on each of those steps as best I can. You indicated that there was a system involved.

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A. It's an application.

Q. I think I've seen some documents that indicate the FUL process was computerized?

A. Correct.

Q. Right? Is that what you're talking about when you talk about the system?

A. Yeah. It's an application that they use.

Q. And what kind of application is it?

A. I'm not a techie person. I don't know. It's on the computer. It's an application. I don't know what more -- how to describe it.

Q. Was the application set up before you started working on it or did you --

A. No.

Q. -- take part in setting it up?

A. When I first started working on FULs it was in our mainframe. The activity would occur in our mainframe. They took it from the mainframe and put it into an application that they can use on the computer, if that helps.

Q. And do you recall -- was there someone -- you mentioned systems folks. Was there somebody at

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CMS in the systems department that was involved in this?

A. In the switch to the new application?

Q. Yeah. And basically the FUL program in general. Who was involved in loading data --

A. The systems support was Dona Kaufman. D-o-n-a.

Q. Was there anyone else you recall or was she the primary person?

A. There was someone before her, but he no longer works for CMS and I can't remember his name. But she was the main one for the new application.

Q. Do you know if she's still there today?

A. Yes.

Q. Do you recall when the new application -- when you moved from the mainframe to the new application?

A. Time?

Q. Yes. When that happened.

A. After '95.

Q. Prior to 1995 was the process still computerized bringing in information from the

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compendia and that kind of information?

A. It was brought into the mainframe.

Q. Just brought into a different computer in other words? I'm not a techie either.

A. I'm just saying mainframe because that's what I know.

Q. And do you know what the application is called?

A. FULs.

Q. FULs. Now, the Orange Book has a place in this process, correct?

A. Right.

Q. And could you tell us what the Orange Book is and what impact it had?

A. The FDA Orange Book. It lists the drugs that are grouped by the FDA. If you have an Orange Book available, I think they have on the front page -- yeah -- the Orange Book can explain it much better than I can. But -- yeah.

Q. I'm handing you our only copy of the Orange Book.

A. But they get this electronically and it

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just has drugs by ingredient names. And they don't have NDC numbers or anything in here. But they pull data from the Orange Book where the criteria that's in the regulation -- so it meets that criteria. And they just pull what they can from there. There's other type of system criteria in there that picks the drugs that are selected for the FULs. But it pulls it from the Orange Book first.

Q. So they have an electronic version of the Orange Book?

A. They -- it's my understanding they do now.

Q. Do you know when they first started using an electronic version of the Orange Book versus some other method of getting the Orange Book data into this computer?

A. I really don't know.

Q. Do you recall at some point somebody had to go through the manual copy of the Orange Book --

A. Oh, no. They wouldn't go through the manual. They would just request the data from FDA. I think the data now is available and they could go

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on the Web or someplace in FDA's website and obtain the data now.

Q. But it was all done to your knowledge -- as far as you can recall it was done electronically in some way?

A. Correct.

Q. Somebody would set up a program that would, say, identify the drugs that meet the FUL criteria and then down those into a file, something called Orange Book or something like that? Is that how it worked?

A. You would have to talk to our systems folks. I just know that they would get -- they had the criteria set in there and however it works, you know. I mean, we're simplifying it, but I'm not a data person. We just tell them what we need from the Orange Book and they set up their criteria on how they're going to get it and how it's selected.

Q. And do you recall what the criteria was for a drug to qualify for the FUL program?

A. I'm going to read it from here. But it says -- well, all the formulations of the drug

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products approved by the FDA are A-rated which are therapeutically equivalent and then there must be two rated A in the Orange Book. And then there's another criteria where they can also allow a B-rated drug when the A-rated drug products -- when there's three A-rated drug products in the Orange Book.

Q. Okay. So if not all the drugs within a drug product group are rated A, then you have to have three that are rated A?

A. Correct, to allow a B-rated product.

Q. Now, would the B-rated product or a product that's not rated A, would that still be governed by the FUL?

A. If it's included in this, yes.

Q. What involvement would you have in the review of the Orange Book data and what gets on the Orange Book lists in the computer?

A. I have nothing to do with that.

Q. Who was involved in that?

A. If you're saying reviewing it --

Q. Just who was involved in deciding which drugs from the Orange Book, whether it be manual or

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electronic, get put into your FUL computer?

A. The system folks would download the drugs from the Orange Book. If further review is needed, if some of the drugs are questionable, if they met the criteria and maybe weren't on there before, then we would look at those drugs to verify that they did meet the criteria.

Q. Let me ask you a specific question here. And I'll give you my copy of this.

MR. TORBORG: And Ms. Martinez, you can look on with her if you'd like.

MS. MARTINEZ: I'm going to try to stay away from that videotape.

THE WITNESS: Thanks.

BY MR. TORBORG:

Q. Specifically, on this top page, the right column is a drug under the prescription drug product list by the name vancomycin hydrochloride.

MS. MARTINEZ: Give me one second just to glance at what it is.

Counsel, would you like to lay out a little bit of foundation, like maybe the date of the

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A. I don't know.
Q. Have you ever seen a policy memorandum or any other memorandum that discusses why injectables are specifically excluded from the FUL program?
MS. MARTINEZ: Objection, form.
A. I'm not aware of that.
Q. Are you aware of any other criteria that HCFA has used to eliminate drugs that might otherwise satisfy the regulatory or statutory criteria?
A. I think unit dose.
Q. Can you explain a little bit -- that unit stuff always makes my head spin.
A. Just the little individual unit dose packets, like little individual blister tablets that might be in the little blister pack that are generally distributed within a hospital setting.
Q. And why are those -- do you understand why those are excluded?
A. Here again, what I think they're trying to focus on is what's the drugs that are commonly used and dispensed by the pharmacies.

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Q. Any other exclusion criteria that you're aware of?
A. They may not want to capture the infusion bags because here again that's generally used in an impatient setting and not dispensed at the pharmacy.
Q. Do you know if that's the fact that the FUL program does not cover infusion bags? Is that something that you're aware of?
A. As far as I know they don't.
Q. And infusion bags would be what type of products?
A. I really can't say at this point.
Q. Saline solution?
A. Okay, fine.
Q. Is that one?
A. Yeah.
Q. Dextrose-type solutions?
A. That's my understanding.
Q. And the rationale for exclusion of those is the same as the rationale for excluding the injectable drugs?
A. Correct.

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Q. Any other criteria you're aware of?
A. That's all I can think of.
Q. And do you know if the blister pack or the infusion bag exclusions are written down anywhere?
A. I'm not aware of that.
Q. Are -- I'm sorry.
A. The systems folks, they might have written criteria. I really don't know and I can't speak for them. But I'm not aware of any.
Q. Do you recall any discussions about -- apart here today in the deposition, of course -- about why infusion bags, blister packs and injectable drugs are not included in the FUL list?
A. You mean specific discussions?
Q. Or general discussions. Anything you recall.
A. I'm sure that it was discussed over the years just within the process of working on the FULs.
Q. Do you know if HCFA has since changed the way that it does FULs so that any of those three

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categories' exclusions are no longer excluded?
A. I have no idea.
Q. Okay. I think that the next step you discussed was the pulling in of the compendia data --
A. Correct.
Q. -- into the mainframe or later the application, correct?
A. Correct.
Q. And was that done with electronic copies of the compendia data?
A. I don't know. I don't know how they obtained that data. I would assume it's electronic, but I don't know.
Q. But you did not sit down with a copy of the Red Book or the Blue Book, a manual copy, and input things into a computer?
A. No.
Q. Right? What you know is that by the time you got involved somebody had already loaded the data into the system?
A. Correct.

SIGNATURE OF WITNESS

_____

SUE GASTON

Subscribed and sworn to and before me

this _____ day of _____, 20____.

_____

Notary Public